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EXAMINER

SRIVASTAVA, KAILASH C

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Paper No. 18

Application Number: 09/555,906

Filing Date: June 02, 2000

Appellant(s): DRIEU, KATY

Charles A. Muserlian #19,683
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 04/08/2002 (Paper Number 16).

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The brief does not contain a statement identifying the related appeals and interferences, which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal. Therefore, it is presumed that there are none. The Board may, however, exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

Claims 2-8 and 10-13 stand finally rejected.

Claims 1 and 9 have been cancelled.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary is deficient because it does not provide an indication of the pertinent pages of specification wherein the invention is described. The summary of invention contained in the brief is summarized at page 1, line 13 to page 6, line 24 of the instant specification.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. Appellant states that "All of the claims stand rejected under 35 USC 103 as being obvious over the Hsai et al patent and the Kleijnen et al reference taken in view of the Remington's Pharmaceutical Sciences reference." However, claims 2-8 and 10-13 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hsia et al (U.S. Patent 5,976,548), and Kleijnen et al (*Lancet*, 340: 1136-1139, 1992), in view of Osol et al (Remington's Pharmaceutical Sciences, Philadelphia College of pharmacy and Science, 1980) and Park et al (U.S. Patent 5,541,183). It is noted that although Appellant doesn't include the Park et al reference in his statement of the issues, the Park et al. reference is addressed in Appellant's arguments section.

(7) Grouping of Claims

The rejection of claims 2-8 and 10-13 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) ClaimsAppealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

The prior art relied upon by the Examiner in the rejection of the claims under appeal is as follows:

5,976,948 Hsia et al. 11-1999

5,541,183 Park et al. 07-1996

Kleijnen et al., "Ginkgo biloba" The Lancet, Vol. 340 (November 7, 1992), pages 1136-1139.

Osol, A. et al (Eds.). Remington's Pharmaceutical Sciences. Philadelphia College of Pharmacy and Science. 1980. pp. 1287, 1290-1293, 1295-1296.

Note that Park et al is not listed in the "Prior Art" section of appellant's brief.

(10) Grounds of Rejection

Claims 2-8 and 10-13 stand finally rejected under 35 U.S.C. §103(a) as unpatentable over Hsia et al. (U.S. Patent 5,976,948) and Kleijnen et al. (Lancet, Vol. 340, pp.1136-1139) in view of Osol et al. (Remington's Pharmaceutical Sciences, Philadelphia College of Pharmacy and Science, 1980, pp. 1287,1290-1293 and 1295-1296) and Park et al. (U.S. Patent 5,541,183).

Appellants' claims are drawn to a "method to ease withdrawal symptoms of substance abuse" in a human being, such ease being effected by administering a ginkgo extract preparation. The said ginkgo extract contains 5-50% ginkgolides. The said ginkgolides are selected as pharmaceutical salts of a ginkgolide, or glycosylated, alkoxylated or acetylated ginkgolide.

Hsia et al. teach a method wherein administering a composition containing

ginkgo extract helps overcome headaches, absent-mindedness and confusion (column 4, lines 34-39).

Kleijnen et al., disclose that their ginkgo extract has been used in methods to treat headache, dizziness, and depression (See, e.g. Kleijnen et al., Page 1138, Column 2, lines 46-54). The said ginkgo extract contains ginkgolides A and B and the concentrations of these ginkgolides available to the subject in their ginkgo extract is 50-70% (See Kleijnen et al., Page 1138, Column 1, lines 38-45). Kleijnen et al., also disclose treatment of cerebral insufficiency through administration of ginkgo extracts (Page 1136, Column 1, lines 42-45). Cerebral insufficiency includes headache, absent-mindedness, depression and dizziness (Page 1136, Column 2, lines 1-4).

Thus, both Hsia et al., and Kleijnen et al. disclose methods wherein ginkgo extracts are administered to treat headache, absent-mindedness and confusion. However, neither Hsia et al. nor Kleijnen et al. specifically teach the symptoms of substance abuse withdrawal.

Osol et al., however, define the symptoms of substance abuse withdrawal in an individual who withdraws from addiction of alcohol, alcohol abuse, cigarette smoking, or amphetamine abuse to be manifested as headache, confusion, disorientation and hallucination (Page 1291, Column 1, Paragraph 1; page 1292, column 1-2).

Therefore, at the time that the invention was made, it would have been obvious to an artisan of ordinary skill to treat the symptoms of substance abuse withdrawal by administering *Ginkgo biloba* extract to the individual exhibiting the aforementioned symptoms, because said symptoms are manifested as headache, confusion, etc. in an individual undergoing withdrawal from addiction of substance abuse and Hsia et al. (column 4, lines 34-39) and Kleijnen et al. (Page 1138, Column 2, lines 46-53) teach that these manifested symptoms of substance abuse withdrawal are treatable by administering *Ginkgo biloba* extract.

The references cited *supra* (Hsia et al., Kleijnen et al., and Osol et al.) do not teach all of Appellant's embodiments. However, the adjustment of particular conventional working conditions (e.g., determining the result effective

amount/range of ginkgolides or other constituents of ginkgo extract and/or preparing a therapeutic composition such as a pharmaceutical) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan and therefore obvious at the time the invention was made. This is particularly true in an art as old and well developed as the pharmaceutical use of *Ginkgo biloba* extracts. Further, Park et al teach or provide guidance to methods of making and using pharmaceutical compositions containing the claimed ginkgolide derivatives and administer them in pharmaceutical compositions for the same effect (i.e., to ease symptoms of substance withdrawal) as the natural *Ginkgo biloba* extracts. Park et al., disclose methods to synthesize ginkgolide B derivatives that are acetylated and alkoxyated (Column 6, lines 4-6) and disclose methods to prepare pharmaceutical compositions containing aforementioned ginkgolide B derivatives. Learning from the teachings of Park et al. about methods to synthesize acetylated and alkoxylated ginkgolides, an artisan of ordinary skill would have been motivated to prepare glycosylated ginkgolides through substituting ginkgolide B compositions of Kleijnen et al., with mono-, di-, or polysaccharides and to synthesize pharmaceutical compositions by incorporating those substituted ginkgolides according to the method of Park et al. Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to optimize the compositions of Hsia or Kleijnen by routinely making derivatives of gingkolides as suggested by Park and use them in the pharmaceutical compositions of Hsia or Kleijnen with a reasonable expectation of success in achieving a similar or even better pharmacological reactions.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use *Ginkgo biloba* extracts to alleviate the symptoms of withdrawal because said symptoms are known to be manifested as headaches, confusion, etc. and the art clearly teaches that those symptoms can be alleviated by the administration of *Ginkgo biloba* extracts.

(11) Response to Argument

Appellant argues that the prior art references that the examiner has cited in no way suggest a method wherein *Ginkgo biloba* extract has been applied to alleviate the "withdrawal symptoms of substance dependency or addiction in a

human". Also argues the Appellant that, "there is no suggestion to combine the prior art references as the Examiner has done" in order to obtain the Appellant's claimed invention. Appellant's arguments regarding the Prior art references have been fully considered, but are not found persuasive.

In response to Appellant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Hsia and Kleijnen both teach administration of gingko biloba extracts for the alleviating of headaches, etc. Osol is cited and combined only in that it serves to define what the symptoms of withdrawal are.

The appellant also argues on page 5, lines 8-10, of the appellant's Brief that "There is not one iota of a suggestion of alleviating withdrawal symptoms of substance dependency or addiction in a human" in the examiner cited prior art reference (i.e., Hsia et al.). Appellant's argument is not persuasive because Hsia et al. teach a composition comprising *Ginkgo biloba* extract, which treats headache. As is learnt from Osol et al., headache is one of the symptoms of substance abuse withdrawal, and headache is eased or treated with Hsia et al.'s composition comprising *Gingko biloba* extract. Since the same composition treats the same symptom, Hsia et al. clearly teaches a method to ease symptom of substance abuse withdrawal.

Argues further the appellant on page 6, lines 12-16, "One skilled in the art would not have guessed in an obvious manner that a drug used for decades and even centuries for completely different purposes such as memory improvement or venous efficiency would be useful for easing withdrawal symptoms of narcotics and the like." This argument is also not persuasive in view of Hsia et al. and Osol et al. Hsia et al. clearly teaches both memory enhancement and easing headaches with administration of Hsia et al.'s composition comprising *Gingko biloba* extract, while

Osol et al. define both headache and memory loss as symptoms of substance (e.g., cigarette smoke, clearly a narcotic) abuse withdrawal.

Simply put, as we know from Osol, the symptoms of withdrawal are manifested by headache, confusion, etc. and one of ordinary skill in the art at the time the invention was made knew that gingko biloba extracts could be used to alleviate those manifested symptoms. Therefore, it would have been obvious to treat the symptoms of withdrawal with gingko biloba extracts and reasonably expect that the symptoms would be alleviated.

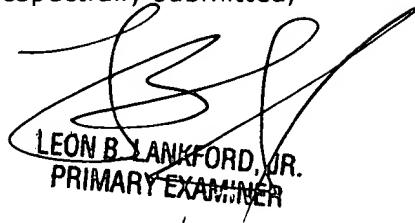
Appellant argues on page 6, lines 12-13, that *Ginkgo biloba* extract is "a drug used for decades and centuries for completely different purposes", purposes that according to Examiner cited prior art encompass memory improvement and headache treatment. Both of these symptoms are also symptoms of substance abuse withdrawal. Therefore, the appellant is suggesting a hitherto known use for a known composition, an unpatentable invention under 35 U.S.C. § 103(a).

Thus, Appellant's arguments have been considered. However, these arguments are not persuasive because a showing to overcome a *prima facie* case of obviousness must be clear and convincing and commensurate in scope with the claims. Appellant's arguments starting with "It should be noted from the" on page 6, line 16, and ending with "muscles and the like" on page 6, line 21 of appellant's Brief are not commensurate in scope with the claims presented in the instant application. The claims are drawn to the "alleviating of symptoms" without reference to specific symptoms or all symptoms.

In sum, Claims 2-8 and 10-13 fail to be patentably distinguishable over the state of the art discussed above. Therefore, the claims are properly rejected under 35 U. S. C. § 103 (a).

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



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June 16, 2002



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